GOODSILL ANDERSON QUINN & STIFEL
A LIMITED LIABILITY LAW PARTNERSHIP LLP

EDMUND K. SAFFERY 5860-0
esaffery@goodsill.com
WAYNE R. WAGNER 10012-0
wwagner@goodsill.com
MATTHEW D. EZER 10953-0
mezer@goodsill.com

First Hawaiian Center, Suite 1600
999 Bishop Street
Honolulu, Hawaii 96813
Telephone: (808) 547-5600
Facsimile: (808) 547-5880

LATHAM AND WATKINS LLP

PHILLIP J. PERRY (*pro hac vice* forthcoming)
ANDREW D. PRINS (*pro hac vice* forthcoming)
ABID R. QURESHI (*pro hac vice* forthcoming)
555 Eleventh Street, NW
Suite 1000
Washington, D.C. 20004-1304

Attorneys for Plaintiff
PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff,	CIVIL NO. _____

vs.

ANNE E. LOPEZ, IN HER OFFICIAL CAPACITY AS ATTORNEY GENERAL OF HAWAI‘I

Defendant.

COMPLAINT FOR DECLARATORY AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

1. Recently enacted Hawai‘i House Bill 712 (“H.B. 712”) violates the United States Constitution’s Supremacy Clause. Plaintiff Pharmaceutical Research and Manufacturers of America (“PhRMA”) brings this Complaint and states as follows:

PRELIMINARY STATEMENT

2. H.B. 712 is Hawai‘i’s attempt to rewrite the terms of a federal program known as the 340B Drug Pricing Program, 42 U.S.C. § 256b (“340B”). The substance and subject of the state law is unequivocally a federal drug pricing program reflecting a delicate, carefully calibrated balance struck by the United States Congress. State laws that attempt to rework that federal program are preempted. *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 453-60 (S.D. W. Va. 2024) (preliminary enjoining state 340B statute as likely preempted); *cf. Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011) (holding common law remedy displaced because Congress trusted federal agency alone with administration of 340B).

3. 340B was enacted in 1992 as a unique form of privately funded federal subsidy. It requires that drug manufacturers make an “offer” to sell certain of their drugs to 15 statutorily enumerated types of healthcare providers (“covered entities”) at “strikingly generous” prices—often “penn[ies] per unit.” *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024); 42 U.S.C. § 256b(a)(1)-(4).

Covered entities, in turn, are limited in what they can do with 340B-priced drugs: By statute, they are barred from selling *or* transferring 340B-priced drugs to anyone other than their patients, which is known as "diversion." 42 U.S.C. § 256b(a)(5)(B).

4. Congress could not outright mandate these penny-price sales by manufacturers—doing so would invite constitutional challenge. Instead, Congress struck a specific bargain with drug manufacturers reflecting a careful balance of interests: If drug manufacturers agree to make a bona fide *offer* to sell certain drugs at 340B prices to covered entities, those drugs would also be eligible for reimbursement under Medicare Part B and the federal share of Medicaid. Otherwise, they would not. As two federal Courts of Appeals have made clear, Congress's chosen "offer" framework permits drug manufacturers to impose reasonable conditions on the offers they are required to make to covered entities. *See Novartis*, 102 F.4th at 460-61; *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 703-06 (3d Cir. 2023). Under fundamental principles of contract law, if covered entities accede to those conditions, they accept the terms of the offer and may purchase 340B-priced drugs. *See infra* ¶¶ 10-12, 40, 44-45, 91-97, 124; Williston on Contracts § 6:11 (4th ed.) ("Thus, if an act is requested [as part of an offer], that very act and no other must be performed."). If covered entities reject the conditions, the offer is rejected and no purchase of the 340B-priced drugs occurs. Williston on Contracts § 6:11 ("[B]ecause the offeror is entitled to receive

what it is it has bargained for, if any provision is added to which the offeror did not assent, the consequence is . . . that the offer is rejected, and that the offeree's power of acceptance thereafter is terminated.").

5. To incentivize continued participation and maintain uniformity, Congress authorized the U.S. Secretary of Health and Human Services, superintended by federal courts, to administer and enforce 340B through a range of carefully balanced and exclusive federal mechanisms. 42 U.S.C. § 256b(d). Those mechanisms include a unique administrative dispute resolution ("ADR") scheme run by the U.S. Health Resources and Services Administration ("HRSA"), an agency within the Department of Health and Human Services ("HHS"). *Id.* Congress intended HHS to "hold the control rein" to ensure that 340B would be administered "harmoniously on a uniform, national basis." *Astra*, 563 U.S. at 120. The Supreme Court ruled that this enforcement mechanism was the exclusive remedy for disputes about the operation of 340B. *Id.* at 119-22. In so holding, it found that third-party suits to enforce the law were incompatible with the statutory regime. *Id.* at 120.

6. At the heart of this litigation is an effort to protect the integrity and viability of 340B by honoring the bounds Congress set for the program. Congress created 340B to help underserved patient populations of covered entities. But in recent years, 340B has become a lucrative moneymaker for national pharmacy

chains, who are not supposed to benefit from the program, and others who seek to enrich themselves at the expense of these underserved patients.

7. Over the past decade, concerns about diversion and illegal "duplicate discounts" in the 340B program have skyrocketed as covered entities have teamed up with so-called "contract pharmacies"—mostly for-profit pharmacies—nationwide to find ways to maximize the volume of 340B drug price reductions. Under the now prevailing product "replenishment model," contract pharmacies first order drugs at market prices, and then, following sale of those drugs, seek to replenish their inventories with 340B-priced drugs by retroactively identifying, via black-box algorithms, drugs that are purportedly eligible for 340B pricing.

8. As a result, the volume of drugs purchased at reduced 340B pricing has exploded. In 2023, discounted 340B purchases reached a record *$66.3 billion*, a $12.6 billion increase from 2022 and a $61 billion increase from 2010. *See infra* ¶¶ 38-39. Those 2023 purchases reflect manufacturer-provided discounts of *$57.8 billion* from market rates. *Id.* Almost no 340B price reductions are passed on to patients. *See* IQVIA, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, https://tinyurl.com/3d4tk9ae.

9. The United States Government Accountability Office ("GAO") and the HHS Office of the Inspector General ("OIG") have warned about the risks of abuse created by the use of contract pharmacies and the product replenishment model. *See*

infra ¶¶ 63-64. Manufacturers, including many PhRMA members, have identified specific concerns and independently adopted policies to address them. *See infra* ¶ 85. Although the exact contours of the policies differ, they are all intended to curb abuse, and generally (1) provide a limit on the number of outside pharmacies with which a covered entity may contract to receive 340B-priced drugs, such as so-called "one contract pharmacy policies," and (2) require the contract pharmacy to submit data supporting their claims for the 340B-priced drugs, referred to as "claims data policies," as a condition precedent to receiving 340B-priced drugs.

10. Both the D.C. and Third Circuits have held that, under federal law, these types of policies are reasonable and permissible conditions drug manufacturers may impose on the 340B offers they make to covered entities. *Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703-06. Specifically, to help prevent 340B drugs from being diverted, manufacturers can include a condition that they will deliver 340B-priced drugs to the covered entity itself or, if the covered entity lacks an in-house pharmacy, one designated "contract pharmacy." *Novartis*, 102 F.4th at 460-64; *id.* at 456-58 (explaining how covered entities' use of an "unlimited" number of contract pharmacies materially changed the nature of the program and substantially inflated the volume of 340B-priced drugs); *Sanofi*, 58 F.4th at 704 ("Congress's use of the singular 'covered entity' in the 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing

in a plethora of pharmacies."). Both courts also held that manufacturers can lawfully include conditions requiring covered entities to provide certain details regarding the prescriptions on which they sought 340B pricing, known as claims data. *Novartis*, 102 F.4th at 463; *Sanofi*, 58 F.4th at 701.

11. If a covered entity, or a contract pharmacy purporting to act on its behalf, does not accept an offer with these conditions, there is no qualifying 340B "purchase" under 42 U.S.C. § 256b(a)(1), and therefore no obligation on manufacturers to provide 340B pricing.

12. In response to adverse federal court decisions interpreting the federal 340B program, covered entities' representatives have turned to the states, including Hawai‘i, arguing that states can bar the very same conditions that federal law expressly permits these manufacturers to impose.

13. State officials recognized that H.B. 712 would be entering a domain under federal control. For example, in testifying before Hawai‘i's House Committee on Health and House Committee on Human Services & Homelessness, the Hawai‘i Department of Health noted that, although there was a "need for someone to do something" about the 340B program, the fix had to come from Congress. *Joint Pub. Hearing, Comm. On Health, Comm. On Human Servs. & Homeless* at 36:13-36:40 (Jan. 31, 2025) ("[T]here is a need for somebody to do something about this [but] that's really got to be Congress at this point"),

https://www.youtube.com/live/4V4O8Yrs1-E. And representatives recognized how intertwined H.B. 712 was with the federal program, questioning testifiers on the intent of the 340B program. *House Pub. Hearing, Comm. On Consumer Prot. & Com.* at 1:52:32-1:54:15 (Feb. 11, 2025) (Representative Scot Z. Matayoshi asking the Healthcare Association of Hawai‘i about the intent of Congress in enacting 340B), https://www.youtube.com/live/Q1N4koVMawA; *see also House Pub. Hearing, Comm. On Judiciary & Hawaiian Affairs* at 15:42-16:07 (Feb. 25, 2025) (Representative David A. Tarnas introducing H.B. 712 as a bill related to the "federal 340B drug pricing program" and welcoming the Department of Health "to tell us what this actually means"), https://www.youtube.com/live/EjK1khKNiSs.

14. This type of interference in a purely federal program is preempted. As one court has already held, laws that take enforcement control over the federal program from the federal government by imposing a state enforcement regime violate the Supremacy Clause. *Morrisey*, 760 F. Supp. 3d at 458 (holding that the Supreme Court in *Astra* "has already found that such attempts to enforce 340B are contrary to law").

15. That conclusion equally applies to H.B. 712. In multiple ways, H.B. 712 purports to change the requirements of the federal 340B program and the conditions under which manufacturers provide their drugs at reduced prices. That violates the Supremacy Clause.

16. **First**, the law explicitly prohibits manufacturers from undertaking actions that are fully permissible under federal law and that can be imposed as a condition as part of the manufacturers' offer of 340B-priced drugs, as determined by multiple federal courts. H.B. 712 Sec. 2, § 2. For example, whereas Congress categorically *did not* require manufacturers to provide 340B-priced drugs to unlimited numbers of contract pharmacies, H.B. 712 mandates it. In doing so, H.B. 712 seeks to compel transactions at the 340B price where they would not otherwise occur under federal law. That not only violates the federal statute, but also fundamentally alters the bargain struck by Congress for manufacturer participation in 340B, which is reflected in agreements between manufacturers and the federal agency.

17. **Second**, H.B. 712 impermissibly intrudes on the exclusive federal enforcement regime that Congress established. H.B. 712 attempts to open the same door for private suits to enforce federal 340B requirements that the Supreme Court explicitly slammed shut in its unanimous 2010 opinion in *Astra*. *See* H.B. 12 Sec. 2, §§ 3-4. As the Supreme Court explained, Congress "authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling" and that bar cannot be circumvented by "dress[ing] their claims" in other "clothing." *Astra*, 563 U.S. at 113-14.

18. In addition, as the Supreme Court's *Astra* opinion also makes clear, Congress in 2010 chose to address a series of 340B disputes between healthcare providers and drug manufacturers by creating a detailed series of federal remedial provisions, administered by the federal agency. The agency itself has concluded that those federal remedies would address exactly the same issues H.B. 712 seeks to regulate. 89 Fed. Reg. 28,643, 28,649 (Apr. 19, 2024). Yet Hawai'i believes it can create its own competing enforcement regime. As the U.S. Supreme Court already explained in *Astra*, "recognizing [covered entities'] right to proceed in court could spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities," wresting control from the federal government and creating "substantial" "risk of conflicting adjudications." 563 U.S. at 120. Among other things, a Hawai'i decisionmaker will need to decide multiple questions of federal law before imposing liability for a suit brought by a private entity or the Hawai'i Attorney General. 42 U.S.C. § 256b(a)(4)-(5). If Hawai'i and other states are permitted to render decisions on these core federal issues, the uniform federal program will cease to be federal or uniform, again contradicting the Supreme Court's reasoning in *Astra*.

19. **Third**, H.B. 712's penalties conflict with the carefully balanced provisions in the federal statute. H.B. 712 imposes penalties, including a penalty of up to $2,500 for each violation, with "[e]ach day that a violation" occurs constituting a "separate violation." H.B. 712 Sec. 2, § 4(b). The Act also provides for these

penalties to be "cumulative to the remedies or penalties available under all other laws of the State" and allows a court to award "disgorgement and any other equitable relief it considers appropriate." *Id.* § 4(b)-(c). The threat of these severe penalties imposed by states, including Hawai'i, will transform 340B into something Congress never intended. Drug manufacturers may decide to opt out of key federal programs as a result, defeating the carefully balanced purposes of 340B entirely. *See Astra*, 563 U.S. at 120; *see also Novartis*, 102 F.4th at 462 (noting federal government's argument that 340B's "enforcement scheme is carefully calibrated, which tends to suggest that it is exclusive").

20. This expansion of 340B beyond federal bounds is lining the pockets of for-profit pharmacies and administrators, which were never intended to benefit from 340B. As reflected in a recent report from the Minnesota Department of Health, approximately $1 out of $6 of gross revenue by covered entities nationwide went to contract pharmacies and third-party administrators, who run the black-box algorithms to find allegedly 340B-eligible patients. Minn. Dep't of Health, *340B Covered Entity Report* at 9 (Nov. 25, 2024), https://tinyurl.com/ysrsex84. Both CVS and Walgreens, for example, have publicly disclosed that 340B profits are material to their finances and that a reduction in contract pharmacy arrangements "could materially and adversely affect" their finances. CVS, SEC Form 10-K at 23 (2024), https://tinyurl.com/4pbtt9x8; Walgreens, SEC Form 10-K at 30 (2024),

https://tinyurl.com/zp9vv465; *see also* S. Comm. on Health, Educ., Lab., & Pensions, Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program 26-27 (Apr. 2025) (reflecting CVS's third-party administrator, Wellpartner, generated $1.6 billion in revenue from covered entities from 2019 to 2023 through third-party administrator fees), https://tinyurl.com/3rh429c9.

21. H.B. 712 attempts to regulate in an exclusively federal field and, worse, directly conflicts with the federal statute. It is both field and conflict preempted under the Supremacy Clause.

22. PhRMA brings this action to declare unlawful this improper state intrusion into the federal 340B scheme and to enjoin preliminarily and permanently Defendant from enforcing H.B. 712 against PhRMA's members and as to the sale of their drugs.

PARTIES

23. PhRMA, a trade association representing the nation's leading innovative biopharmaceutical research companies, advocates for policies that encourage the discovery and development of important new pharmaceutical products.

24. PhRMA's members, which manufacture and sell pharmaceutical products, participate in the federal 340B program and will thus be forced to supply

their drugs at a steeply reduced price under H.B. 712 or otherwise face significant monetary penalties.

25. Neither the claim asserted nor the relief sought in the Complaint requires the participation of any individual member of PhRMA.

26. Defendant Anne E. Lopez is the Attorney General of the State of Hawai‘i and is sued in her official capacity. The Attorney General is authorized under H.B. 712 to bring a civil action to enjoin a violation of Section 2 of the Act. H.B. 712 § 4. The Attorney General has her principal office in this district at 425 Queen Street, Honolulu, Hawai‘i 96813.

JURISDICTION AND VENUE

27. PhRMA's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

28. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

29. This Court has inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*,

209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

30. Venue is proper in this district because this action challenges a Hawai‘i law applicable to the sale of PhRMA's members' drugs in this district, and thus H.B. 712 purports to directly restrict and restrain PhRMA members' conduct in selling and distributing drugs within this district. 28 U.S.C. § 1391(b)(2).

31. Substantial amounts of PhRMA's members' drugs are sold under the 340B program to covered entities in this district. For example, HHS's website reflects that there are numerous covered entity sites in the District of Hawai‘i. *See* HRSA, Covered Entity Search Criteria, https://340bopais.hrsa.gov/coveredentitysearch. The same HHS website reflects that those covered entities maintain a substantial number of contract pharmacy arrangements, including with contract pharmacies in this district. Accordingly, H.B. 712 is likely to be enforced against PhRMA members in this district.

32. Venue is also proper in this district because Defendant maintains her principal office in Honolulu, in this district. 28 U.S.C. § 1391(b)(1).

BACKGROUND

A. The History of 340B

33. Congress established 340B in 1992 to restore drug discounts that had been provided voluntarily by manufacturers to a select group of safety-net providers

before Congress passed the Medicaid Drug Rebate Program ("MDRP") in 1990. Indeed, Congress carefully restricted the list of eligible 340B covered entities to certain enumerated types of entities that "provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992) ("House Report").

34. Prior to the enactment of 340B, drug manufacturers had offered discounts on certain outpatient drugs on a voluntary basis to direct healthcare providers like covered entities, but not to pharmacies. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 29-30 (2019) ("Prior to the MDRP, drug manufacturers regularly offered discounts to . . . hospitals and other safety net providers"). When Congress passed the MDRP in 1990, that law took the manufacturers' previous *voluntary* "large discounts" to safety net providers like covered entities and factored it into the calculation of *required* "best price" for purposes of determining Medicaid rebates. *Id.* at 29-30. The "unintended consequence" of this pricing "snafu" was that drug manufacturers were "disincentivized" from continuing to provide the voluntary discounts they had provided to safety net providers prior to the MDRP's passage. *See id.*; *see also* H.R. Rep. No. 102-384, pt. 2, at 9-10 (1992).

35. Congress created 340B to address the limited problem created by the MDRP's enactment, specifically to restore the discounts that were previously offered voluntarily by manufacturers. *See* Pub. L. No. 102-585, 106 Stat. 4943, 4962; *see also* House Report at 12. When Congress passed 340B, the legislative history indicates that it intended to restore "discounts to these clinics, programs, and hospitals," *i.e.*, "direct clinical care" entities, which had previously received voluntary discounts. House Report at 12.

36. When it passed the 340B law in 1992, Congress estimated that the Program would only include approximately 90 hospitals, 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS drug purchasing assistance programs, a network of hemophilia treatment centers with 150 facilities, and 2,225 health centers that qualified to participate. *Id.* at 13.

B. The Operation and Growth of 340B

37. 340B has grown dramatically in the intervening years.

38. In 2023, 340B purchases reached a record *$66.3 billion*, a $12.6 billion increase from 2022 and a $61 billion increase from 2010. Adam J. Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://tinyurl.com/59ckpy5w; Karen Mulligan, Ph.D., *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, Univ. of S.

Cal. (Oct. 14, 2021), https://bit.ly/3FFSemV. There has been no similar increase in the relevant underserved patient populations that could explain this explosive growth.

39. With the list price value (*i.e.*, based on wholesale acquisition cost) of 340B purchases rising to $124.1 billion in 2023 alone, Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023* 6, IQVIA (2024), 340B has become the second largest government pharmaceutical program, exceeded only by Medicare Part D. Adam J. Fein, *The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://tinyurl.com/44yz9b3d.

40. 340B is supposed to be governed by a federal statutory framework. Under 340B, participating manufacturers "*shall offer*" to each "covered entity" (as delineated by the federal 340B statute) certain outpatient drugs (also specified by statute) at or below a price (again set by statute), *if* such drugs are offered to any other purchasers, meaning manufacturers must make a genuine offer to covered entities for purchase of 340B-priced drugs. 42 U.S.C. § 256b(a)(1). That requirement does not involve an obligation to provide 340B-priced drugs to an unlimited number of contract pharmacies. *See infra* ¶¶ 44-45, 91-97, 124.

41. Federal law defines "covered entity" for purposes of 340B to mean an entity that "is one of" 15 types of specifically enumerated categories of healthcare

providers, 42 U.S.C. § 256b(a)(4), and that meets other specifically enumerated requirements, including that the entity does not engage in an unlawful transfer of 340B-priced drugs and does not seek or cause a duplicate Medicaid discount (*see infra* ¶ 46). 42 U.S.C. § 256b(a)(5).

42. Federally Qualified Health Centers, children's hospitals, critical access hospitals, sole community hospitals (*i.e.*, hospitals geographically isolated from other hospitals, 42 U.S.C. § 1395ww(d)(5)(D)(iii)), and certain other clinics and hospitals are all specifically defined as "covered entities" eligible to enroll and participate in 340B. 42 U.S.C. § 256b(a)(4); *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820-22 (D.C. Cir. 2020). Retail pharmacies are not among the listed covered entities.

43. Federal law defines the "ceiling price" for purposes of 340B to mean "the maximum price that covered entities may permissibly be required to pay for the drug." 42 U.S.C. § 256b(a)(1). That ceiling price is deeply reduced compared to the drug's market price.

44. Manufacturers must "offer" their covered outpatient drugs at or below the applicable "ceiling price" to "covered entities," and only "covered entities" may receive this pricing under the express terms of federal law. *See id.*

45. Identifying the specific obligations imposed by 340B's "shall offer" provision on drug manufacturers requires the interpretation of 42 U.S.C.

§ 256b(a)(1). According to courts that have reviewed this question to date, a drug manufacturer must provide some meaningful path for covered entities to obtain these medications at the 340B price. *See* 42 U.S.C. § 256b(a)(1); *Novartis*, 102 F.4th at 462-64; *Sanofi*, 58 F.4th at 703. But the statute does not mandate a commitment to provide 340B-priced drugs to an unlimited number of contract pharmacies of a covered entity's choosing. *Novartis*, 102 F.4th at 461 ("The requirement to 'offer' drugs at a certain 'price' does not prohibit distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree."); *see also Sanofi*, 58 F.4th at 703.

46. The 340B statute, in turn, forbids covered entities from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), demonstrating that 340B is intended to be a closed system.

47. Manufacturers "opt into" 340B by signing a uniform federal contract with HHS "for covered drugs purchased by 340B entities." *Astra*, 563 U.S. at 113. That uniform contract is known as the "Pharmaceutical Pricing Agreement" ("PPA"). *Id.* at 117. PPAs do not vary between manufacturers, but "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 118.

48. If HHS determines that a manufacturer breached its 340B obligations, HHS can terminate the PPA and remove the manufacturer from the 340B program. *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-13 (Dec. 12, 1996). And if the manufacturer is removed from the 340B program, its medicines will no longer be eligible to receive reimbursements under Medicaid and Medicare Part B, which would have a profound impact on many vulnerable patient populations. *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5), (b)(4)(B)(v).

49. Given the stakes for Medicare Part B and Medicaid and their patient populations, Congress chose to assign oversight and enforcement responsibilities exclusively to HHS to ensure the delicate balance that maintains manufacturer participation. HHS, in turn, has delegated 340B's oversight and enforcement to its component agency, HRSA. Neither the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation of the 340B program. Indeed, the Supreme Court made that clear in *Astra*, holding that the administration and enforcement provisions established an exclusive system of federal management designed to be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120.

50. Congress carefully specified the exclusive mechanisms available for administering 340B disputes and violations: audits, ADR, and an enforcement scheme directed by HHS. For instance, the statute specifies that manufacturers have

a right to audit covered entities to ensure that the covered entity is complying with the 340B program's requirements. 42 U.S.C. § 256b(a)(5)(C). Manufacturers, in turn, are also subject to compliance audits. *Id.* § 256b(d)(1)(B)(v).

51. The imposition of penalties for violating 340B is directly committed to HHS: HRSA evaluates manufacturers' compliance with the 340B statute's requirements and may seek to have HHS impose civil monetary penalties of up to $7,000 on manufacturers that purposefully charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs. 42 U.S.C. § 256b(d)(1)(B)(vi) ($5,000, adjusted for inflation). "Overcharging" refers to charging a covered entity a price above the applicable 340B "ceiling price."

52. 340B also provides for resolving 340B disputes between manufacturers and covered entities via an ADR process to be established through "[r]egulations promulgated by the Secretary [of HHS]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. § 256b(d)(3)) (amending the statute to require HHS to promulgate regulations establishing ADR).

53. These regulations must "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price . . . and claims by

manufacturers that violations of [statutory prohibitions on unlawful transfers of 340B drugs and duplicate discounts] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)); *see* 42 C.F.R. § 10.20 (setting out requirements for ADR review panels).

54. HRSA regulations also must be designed with such safeguards and "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii).

55. To ensure finality and repose, the statute provides that "administrative resolution of a claim or claims . . . shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

56. Federal regulations issued in 2024 make clear HRSA's view that it has federal statutory authority to address issues regarding manufacturer contract pharmacy policies, including through ADR. *See* 89 Fed. Reg. 28,643, 28,649 (Apr. 19, 2024) (defining overcharge to encompass "a claim that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price or the manufacturer does not offer the 340B ceiling price"). In other words, the federal government believes it has authority to address the same precise subject matter H.B. 712 purports to regulate. *Id.*; 42 U.S.C. § 256b(d)(1)

(covering "overcharges and other violations of the discounted pricing requirements").

57. Covered entities must also comply with requirements under 340B. As explained above, covered entities are prohibited from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) (prohibiting unlawful transfers). Covered entities are also prohibited from seeking or causing unlawful "duplicate discounts or rebates" from manufacturers. *Id.* § 256b(a)(5)(A). Such "duplicate discounting" most often occurs when a covered entity obtains a drug at the 340B price and dispenses it to a Medicaid patient, and the manufacturer then also pays a Medicaid rebate to the state Medicaid agency on the same drug. A covered entity that engages in unlawful transfers or duplicate discounting, which would violate § 256b(a)(5), no longer qualifies as a covered entity under the federal statute. *Id.* § 256b(a)(4) (specifying that to qualify as a covered entity, the entity must "meet[] the requirements described in paragraph (5)"). Whether a healthcare entity qualifies as a "covered entity" is a decision entrusted to the federal government.

C. Contract Pharmacy Abuses

58. As noted above, 340B requires that a manufacturer offer 340B pricing only to a "covered entity." 42 U.S.C. § 256b(a)(1).

59. Retail pharmacies are not "covered entit[ies]," so they are ineligible to receive 340B pricing.

60. But certain private, for-profit entities—including the largest national chain pharmacies—have, in increasing numbers, sought to leverage 340B as a tool to enhance their profitability in a way that Congress never intended. This is typically accomplished through complicated contractual arrangements between a covered entity, a pharmacy, and other entities like a third-party administrator.

61. The core feature of these arbitrage arrangements is that the for-profit pharmacies end up obtaining drugs purchased at the 340B price. These contract pharmacies, however, serve not only patients of 340B covered entities, but the general public as well—despite the fact that 340B-priced drugs are legally permitted to be dispensed only to patients of 340B covered entities. Inevitably, and at great financial benefit to themselves, contract pharmacies sell drugs purchased at 340B prices to patients who are ineligible to receive such 340B-priced drugs. *See infra* ¶¶ 74-76. Contract pharmacies also reap financial benefit when they dispense to 340B-eligible patients: by extracting dispensing fees and a portion of the 340B "spread" (the difference between the 340B price and what payers reimburse them for the drug), for-profit pharmacies divert value Congress intended to go to covered entities and their patients.

62. Between 2010 and 2018, the number of such contract pharmacy arrangements with covered entities exploded, increasing "more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." GAO, GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 10 (2018) ("2018 GAO Report"), https://tinyurl.com/mr4xbp2m. A more recent study put the increase between 2010 and 2020 at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in 340B as contract pharmacies. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program* 4, Berkeley Rsch. Grp. (Oct. 2020), https://tinyurl.com/3rk5v8nu. By 2020, each covered entity used an average of 22 contract pharmacies. *Id.* at 7. As a result, the number of actual claims for 340B discounts nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), https://tinyurl.com/5n7bmw5m.

63. Several federal watchdogs, including the GAO and HHS's own Office OIG, have warned that the growth of these arrangements exacerbates concerns about abuse and unlawful claims for 340B drugs. *See* 2018 GAO Report at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); *id.* at 45 ("The

expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts.").

64. Here is how the system has evolved over recent years: Under the product "replenishment model" now in widespread use by contract pharmacies,[1] the pharmacies sell drugs from their general inventories to all individuals (both 340B covered entity patients and non-340B covered entity patients)—at prices significantly above the 340B price. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. On Health, Educ. Labor, & Pensions*, 115th Cong. 11 (2018) (statement of Ann Maxwell, Assistance Inspector Gen. for Evaluation & Inspections, OIG) ("Maxwell Testimony") ("[M]any contract pharmacies dispense drugs to all of their customers—340B-eligible *or otherwise*—from their *regular* inventory." (emphasis added)), https://tinyurl.com/5n8jdr9n.

65. Then, after subsequent data analysis using undisclosed algorithms, the contract pharmacies purport to retroactively identify individuals with some relationship to a covered entity—purported covered entity "patients" who were not previously identified as covered entity "patients" at the time the drug was dispensed.

[1] A recent U.S. Senate report confirmed: "With the rise of contract pharmacy use in the 340B Program, most covered entities now use the virtual inventory/product replenishment model to dispense 340B drugs." U.S. Sen. Comm. On Health, Educ., Lab. & Pensions, 119th Cong., *Congress Must Act To Bring Needed Reforms To The 340B Drug Pricing Program* 31 (Apr. 2025), https://tinyurl.com/yurm3fey.

Novartis, 102 F.4th at 457 (noting that the third-party administrators who run these algorithms "often receive a larger fee for every prescription deemed eligible for the discount").[2] These black-box algorithms likely result in contract pharmacies claiming prescriptions as 340B-eligible where the individual who was dispensed the drug is not a covered entity "patient." *See* HHS OIG, Mem. Report: Contract Pharmacy Arrangements in the 340B Program, OEI 05-13-00431 16 (Feb. 4, 2014), https://bit.ly/3eWKmBQ.[3] This process operates in an "after-the-fact" manner inconsistent with the specific program guidance published by HRSA. Although that guidance provides that each prescription be verified as 340B eligible at the time of drug dispensing, no prescriptions are verified in this manner under the product replenishment model. *See* 61 Fed. Reg. 43,549, 43,556 (Aug. 23, 1996); *see Novartis*, 102 F.4th at 457 ("Only after dispensing the drugs do these pharmacies

[2] *See, e.g.*, 2018 GAO Report at 2; Maxwell Test. at 11.

[3] HHS OIG has acknowledged this problem. It discussed the following hypothetical: a physician, who practices part-time at a covered entity hospital, gives a prescription to a patient at his private practice. *See* Maxwell Test. at 11. Although this prescription would likely not qualify for 340B, *see* 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015), one contract pharmacy said it would claim a 340B price because it simply matches the name of the prescriber with those who work at a 340B covered entity *at all* (even if only part time), *see* Maxwell Test. at 11. This demonstrates how contract pharmacies can expand the definition of an eligible "patient" to cover additional, non-340B prescriptions. *See also Novartis*, 102 F.4th at 458 (remarking on this very issue).

attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount.").[4]

66. The pharmacies then purchase additional drugs at the 340B price—nominally in the name of the covered entities—to "replenish" the drugs sold previously to the purported covered entity patients. Again, this is done after the fact, without the benefit of data verifying that these retroactively reduced prescriptions were actually 340B eligible.

67. Once those replenishment drugs are received, the cycle starts anew: the 340B-priced drugs are again commingled in the pharmacy's general inventory and dispensed to any individual who walks in the door, regardless of covered entity patient status. Decl. of Krista M. Pedley ¶ 11, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs*., No. 21-cv-00634-PGS-JBD (D.N.J. June 24, 2021), ECF No. 93-2 (HRSA Director of Office of Pharmacy Affairs stating that under the product replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

68. On information and belief, supported by publicly available information, covered entities *do not* retain title to the drugs throughout the process, and contract

[4] This is one reason why purchases of 340B-priced drugs have grown tremendously, while the number of patients treated by covered entities has not. *See* William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program* 5, PIONEER HEALTH (Mar. 2022), https://bit.ly/3MShVog.

pharmacies *do not* act as agents of covered entities and instead serve as independent contractors at most. *See, e.g.*, Walgreens Contract §§ 3.3.5, 8.10, *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-1603 (D.D.C. Nov. 29, 2024), ECF No. 24-2 (showing contract pharmacies take title to the 340B drugs and do not operate as agents of covered entities); Dallas County, 340B Contract Pharmacy Services Agreement – ReCept Pharmacy at 5 (Comm'rs Ct.) ("County shall purchase 340B Drugs through a written contract with the Supplier and shall hold title to such drugs from the time the Supplier fills the order from ReCept [(the contract pharmacy)] made on behalf of the County until the time that ReCept takes delivery of the drugs."), https://tinyurl.com/4wm5d9fd; *see also* Pharmacy Services Agreement Between the County of Monterey and CVS Pharmacy, Inc. at 9, https://tinyurl.com/yr72mhup.

69. Indeed, on information and belief, covered entities do not even know beforehand that a contract pharmacy or a third-party administrator is submitting an order for 340B-priced drugs nominally in its name.

70. As is evident, the product replenishment model seeks to lower the price of drugs for commercial pharmacies and covered entities, not patients—by seeking to replenish contract pharmacy inventories with 340B-priced drugs. There is no dispute that the pharmacies could replenish their inventories by ordering the drugs at market prices, but they instead attempt to do so at 340B prices.

71. On information and belief, the majority of Hawai‘i contract pharmacies operate using the product replenishment model.

72. This product replenishment practice can provide a windfall for covered entities and pharmacies. *See* GAO, GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 5 (2019) (explaining that covered entities "purchase [340B-priced] drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status" and "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"), https://tinyurl.com/bxpnc3ry. As the D.C. Circuit noted, "[t]he covered entity, the pharmacy, and the third-party administrator [who runs the algorithms referenced above] often divvy up the spread between the discounted price and the higher reimbursement rate." *Novartis*, 102 F.4th at 457. Accordingly, "[e]ach of these actors . . . has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457-58.

73. Both CVS and Walgreens, two of the largest for-profit pharmacy retailers, have publicly disclosed that 340B profits are material to their finances. *See supra* ¶ 20.

74. By contrast, patients routinely do not receive the benefit of the discount in the form of lower prescription costs. *See* Summ. J. Hr'g Tr. at 60:2-7, *PhRMA v.*

Murrill, No. 6:23-cv-00997, ECF No. 78 (June 7, 2024) (Counsel for covered entity Intervenors: "Under replenishment, . . . the pharmacy is not going to know that that's a 340B eligible patient. That's not in the record the pharmacy has available."); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?* 3, 12, IQVIA (2022) (concluding that "most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts" and that stakeholders in the 340B program, such as contract pharmacies, are "profit[ing] from 340B revenue"), https://tinyurl.com/mvuy8276; Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023* 6, IQVIA (2024) ("If a substantial number of states pass [policies prohibiting the use of contract pharmacy restrictions], it could further accelerate 340B growth in the coming years" and "reignite the problem of duplicate discounts, since it is difficult to determine the 340B status of prescriptions that are filled at contract pharmacies."), https://tinyurl.com/y9aeb727.

75. Recent evidence continues to reinforce these conclusions. For example, media reporting has revealed how in many cases 340B price reductions are not passed on to vulnerable populations in the form of lower prices. *See* Anna Wilde Matthews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, WALL ST. J. (Dec. 20, 2022) (explaining that many hospitals do not pass on 340B discounts to their patients and that 340B appears to

bolster profits in well-off areas more than helping hospitals in less-privileged neighborhoods), https://tinyurl.com/bdhhzdhr; Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. TIMES (Sept. 24, 2022) (explaining how one hospital "nakedly capitaliz[ed] on" 340B to turn a profit), https://tinyurl.com/28ubr4hd; Joseph Walker, *Employers Get Big Drug Discounts Through Program for Hospitals That Serve Poor Patients*, WALL ST. J. (Mar. 15, 2025) (explaining how sophisticated middlemen help employers tap 340B to save money on prescription drug programs, a far cry from the program's original focus on aiding low-income patients), https://tinyurl.com/y34ctaf5.

76. Similarly, a recent GAO report surveying hospitals found that, of the 30 hospitals surveyed that reported use of contract pharmacies, almost half (14) indicated that they do not provide *any* discounts at contract pharmacies, 10 reported they provide discounts at some contract pharmacies, and only six provided discounts at all contract pharmacies. GAO, GAO-23-106095, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 16 (2019), https://tinyurl.com/49jzmnne. Even among those that do provide discounts, most (10) reported that it varied by pharmacy or patient circumstances, three reported using the patient's co-pay as the "discount," two

reported that they charged more than the 340B price the hospital paid, and only one reported charging less than the 340B price. *Id.* at 17.

77. In Hawai‘i, many contract pharmacies are not even located in low-income districts. A 2024 report from the Pioneer Institute found 62% of 340B pharmacies in the state, supposedly serving the poor, are located in affluent neighborhoods. Pioneer Inst., *340B in Hawaii* (2024), https://tinyurl.com/yc5fwpda.

78. Other state level reports similarly demonstrate that covered entities and their contract pharmacies provide little financial benefit to vulnerable populations. A 2024 report from North Carolina's treasurer focusing on North Carolina's State Health Plan and purchased oncology drugs found that 340B hospitals applied an average markup of 5.4 times their discounted acquisition costs compared to the 2.9 times markup applied by non-340B hospitals. N.C. Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program* 14-15 (2024), https://tinyurl.com/26cxtzw4. And while North Carolina's 340B hospitals reported an average 15.5% net profit margin compared to the 9.4% profit margin for non-340B hospitals, some of the hospitals reporting the lowest levels of charity care were 340B hospitals and 15.6% of 340B hospitals spent less than 1% on charity care. *Id.* at 19-20.

79. This unlawful and unauthorized expansion of the federal 340B subsidy has other repercussions as well. Expanding the subsidy has led to increased

consolidation in the healthcare system, with large hospital beneficiaries snapping up smaller physician providers with "no evidence of hospitals using the surplus . . . to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality." Sunita Desai, Ph.D. & J. Michael McWilliams, M.D., Ph.D., *Consequences of the 340B Drug Pricing Program*, 378 NEW ENG. J. MED., 539, 546 (2018), https://tinyurl.com/nhhtyyah.

80. Besides taking 340B price reductions intended for vulnerable populations, the explosion in contract pharmacy arrangements has also led to an increase in unlawful transfers of drugs purchased at a 340B price. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone "who is not a patient of the [covered] entity"); GAO, GAO-11-836, *Drug Pricing, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (2011) ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."), https://tinyurl.com/yc2mhbeu. Indeed, approximately two-thirds of violations for unlawful transfers uncovered by HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

81. The use of contract pharmacies can also exacerbate unlawful "duplicate discounting." 42 U.S.C. § 256b(a)(5)(A). Unlawful duplicate discounting forces

the manufacturer to provide a discount on its drug twice-over—once under 340B to the covered entity, and again in the form of a rebate to the state Medicaid agency.

82. GAO has found that duplicate discounting happens with outsized frequency when covered entities use contract pharmacies. *See, e.g.*, 2018 GAO Report at 45; *see generally* GAO, GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (2020), https://tinyurl.com/mr38ccjr. As the GAO explains, this is because of the difficulty of auditing and obtaining reliable data for covered entities with "complex" networks of contract pharmacies. 2018 GAO Report at 45.

D. Covered Entities' Repeated Efforts To Expand 340B

83. Covered entities have repeatedly attempted to circumvent federal authority over 340B to impose their own preferred obligations on 340B manufacturers.

84. In 2006, covered entities filed suit against several pharmaceutical manufacturers, claiming that they had been overcharged for 340B-priced drugs in violation of the PPAs between manufacturers and the federal government. *Astra*, 563 U.S. at 116-17. In 2009, on review, the Supreme Court unanimously rejected such private actions as an alternative 340B enforcement mechanism, emphasizing the need for 340B to be uniformly administered with an eye toward implications for other federal healthcare programs. *Id.* at 120. As the Supreme Court held,

"Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Id.* at 117. Rather than allowing "340B entities to launch lawsuits in district courts across the country," with the attendant "risk of conflicting adjudications," "Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 120-21. "Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework *the proper remedy*[.]" *Id.* at 121-22 (emphasis added).

85. Approximately ten years later, with the continued explosion in contract pharmacy arrangements, the increased use of the product replenishment model and documented problems with program integrity, certain PhRMA members independently adopted new and different policies to address the 340B abuses reported by federal watchdogs. *See, e.g.*, First Am. Compl. ¶¶ 48-52; *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027 (D. Del. Feb. 12, 2021), ECF No. 13.

86. In response, the General Counsel of HHS issued a legal opinion on December 30, 2020, purporting to interpret the 340B statute and declaring that "*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." *AstraZeneca Pharms. LP v. Becerra*, 543 F.

Supp. 3d 47, 52-53 (D. Del. 2021). Although the Advisory Opinion was subsequently vacated on other grounds, it demonstrated HHS's understanding that, at a minimum, an agency relationship is required between a covered entity and its contract pharmacy, echoing prior HRSA guidance. 61 Fed. Reg. at 43,550, 43,555 (HRSA 1996 guidance stating that a covered entity without an in-house pharmacy could contract with *one* contract pharmacy to serve as its "agent").

87. In May 2021, HRSA issued letter decisions to the manufacturers that were implementing policies to address 340B abuses, including PhRMA members.[5] Litigation ensued.

88. In the context of those suits, courts have repeatedly concluded that the scope of manufacturers' obligations does not encompass offering or providing 340B-

[5] *See* HRSA, 340B Drug Pricing Program, *HRSA Determines Six Pharmaceutical Manufacturers Are in Violation of the 340B Statute*, Health Res. & Servs. Admin., HRSA Letter to AstraZeneca Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2nybf4z2; HRSA Letter to Lilly USA, LLC Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/5xkem3y7; HRSA Letter to Novartis Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/jytw6xd6; HRSA Letter to Novo Nordisk Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/ycxwceaz; HRSA Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2veh5838; HRSA Letter to United Therapeutics Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2p85wz8d.

priced drugs to an unlimited number of contract pharmacies—the requirement Hawai‘i seeks to impose here.

89. The D.C. Circuit in *Novartis* and the Third Circuit in *Sanofi*, considering two of these lawsuits, began their recent analyses by explaining how the federal statute works and how contract pharmacy and claims data policies interact with it.[6]

90. In *Novartis*, one manufacturer was "willing to work with at least one contract pharmacy designated or previously used by the [covered] entity," so long as the "contract pharmacies provide claims data for contract-pharmacy orders." 102 F.4th at 463. The other manufacturer "intend[ed] to deliver section 340B drugs to a covered entity's in-house pharmacy or to a single contract pharmacy designated by the covered entity." *Id.* at 463-64. In *Sanofi*, two manufacturers permitted the use of "one contract pharmacy" if the covered entity "d[id] not have an in-house pharmacy." 58 F.4th at 701. A third manufacturer similarly permitted the use of "one contract pharmacy" if the covered entity "d[id] not have an in-house pharmacy," but also permitted the use of "an unlimited number of contract pharmacies" if the covered entity "agree[d] to provide claims data." *Id.*

[6] One appeal remains pending. *See Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.).

91. 340B requires that manufacturers "offer each covered entity covered outpatient drugs for purchase' at or below a specified ceiling 'price." *Novartis*, 102 F.4th at 460 (quoting 42 U.S.C. § 256b(a)(1)). The covered entity who receives such an "offer" can then accept the terms of the offer and "purchase" the covered outpatient drugs, or they can decide to not "assent to the same terms" and thus reject the 340B offer. *Id.* (quoting 1 *Corbin on Contracts* § 1.11 (2023)); *see also Sanofi*, 58 F.4th at 703 (holding that manufacturers are required to only "present the drugs [with conditions permitted] for covered entities' acceptance"). Indeed, that Congressional mandate does not "require the offeror to accede to any distribution terms demanded by the offeree." *Novartis*, 102 F.4th at 461; *Sanofi*, 58 F.4th at 703 (holding that the word "offer" does not "imply that the offeror must deliver goods wherever and to whomever the buyer demands"). Where a covered entity rejects the offer, the manufacturer has fulfilled its 340B duty and there is no 340B purchase to which the 340B ceiling price applies. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703-04.

92. The D.C. Circuit rejected the assertion that 340B requires manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *Novartis*, 102 F.4th at 460. As the D.C. Circuit concluded, Congress chose to impose only certain restrictions on 340B-participating manufacturers—most notably that they make a "bona fide" offer, *i.e.*, that they "propose to sell

covered drugs to covered entities at or below a specified monetary amount." *Id.* Congress's judgment means that manufacturers remain free to impose "conditions on the distribution of covered drugs to covered entities." *Id.* at 459-60.

93. And the D.C. Circuit similarly rejected the notion that purported silence allowed for imposition of an unlimited contract pharmacy requirement. As that court noted, purported "silen[ce] about delivery conditions . . . preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Id.* at 460-61. The court also noted that this silence did not mean that manufacturers have carte blanche as to conditions. *Id.* at 462-63. Instead, Congress carefully circumscribed the obligations it placed on manufacturers, only permitting conditions that would not move offers out of the realm of "bona fide" offers. *Id.* The court expressly left to the federal government adjudication of "more onerous conditions" on offers than the ones before it, reviewed by federal courts. *Id.* at 464.

94. The Third Circuit's decision in *Sanofi* likewise rejected the very same obligation Hawai'i seeks to impose here. 58 F.4th at 703-04. The Third Circuit noted that "Congress's use of the singular 'covered entity' in the [statute's] 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*." *Id.* (emphasis added); *id.* at 704 (340B does not "require[] delivery to an unlimited number of contract pharmacies"). The Third Circuit also expressly

enjoined the federal government from imposing this requirement. *Id.* at 706 (barring the federal government "from enforcing against [plaintiffs] its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies"); *id.* at 704 (noting that "'Congress knew how to' grant covered entities permission to contract with third parties for distribution . . . but did not" (quoting *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 36, 39 (2016))).

95. In doing so, the Third Circuit concluded that, despite the statute's "silence" as to the number of permitted contract pharmacies, such an unlimited contract pharmacy requirement "overstepped the statute's bounds," as reflected in 340B's structure and other considerations. *Sanofi*, 58 F.4th at 707. The Third Circuit left open the possibility, however, that the federal obligation may require that manufacturers offer to deliver 340B-priced drugs to some pharmacies in certain circumstances (for example, a single contract pharmacy where a covered entity lacks its own in-house pharmacy). 42 U.S.C. § 256b(a)(1); *Sanofi*, 58 F.4th at 703-04. Thus, *Sanofi* ultimately recognizes there is no gap in 340B into which states can step—instead the question requires interpretation of federal law, specifically what constitutes a bona fide "offer" under 42 U.S.C. § 256b(a)(1). *Id.* at 705.

96. Two other courts are in accord. The U.S. District Court for the District of Columbia, likewise determined in *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783 (D.D.C. Nov. 5, 2021), and the court of appeals affirmed, *Novartis*, 102

F.4th at 455, that the 340B statute permits drug manufacturers to impose reasonable conditions regarding contract pharmacies as part of the manufacturers' participation in 340B, including a reasonable limitation on where manufacturers will send 340B-priced drugs. *Novartis*, 2021 WL 5161783, at *7. In a similar vein, the U.S. District Court for the District of Delaware concluded in *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-59 (D. Del. 2021), that Congress chose not to require manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *AstraZeneca*, 543 F. Supp. 3d at 58-59.

97. The same is true of manufacturers' conditions on their offers of 340B-priced drugs that require covered entities and contract pharmacies to provide certain claims data related to the prescriptions that were purportedly dispensed as 340B drugs. Courts have concluded that manufacturers may impose such conditions (including to help fulfill statutory audit protections), and that those conditions on a 340B offer satisfy the federal obligation. *See Novartis*, 2021 WL 5161783, at *8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of 340B-priced drugs); *id.* ("For its part, [plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B."); *Novartis*, 102 F.4th at 463 (affirming holding).

98. For their part, covered entities have sought to use the federal ADR mechanism, which is overseen by a panel within HHS, to enforce this purported obligation to provide 340B-priced drugs to any and all contract pharmacies identified by a covered entity. In those proceedings, a group of covered entities alleged that a drug manufacturer "ha[d] violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements." Those entities asked the panel "to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order [the manufacturer] to pay Petitioner an amount equal to the 340B discounts that [the manufacturer] has failed to provide." Petition for Damages and Equitable Relief ¶ 1, *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP*, ADR ID: 210112-1 (HHS ADR Bd. Jan. 13, 2021), https://tinyurl.com/2twhwhtc; *see also* Petition for Monetary Damages and Equitable Relief ¶¶ 35-37, *Univ. of Wash. Med. Ctr. v. AstraZeneca Pharms. LP* (HHS Bd. Sept. 29, 2023) (Petition by a different group of covered entities asserting panel has jurisdiction over contract pharmacy disputes).

99. Recently, an ADR Panel within HRSA adjudicated an ADR petition premised on an alleged 340B overcharge violation and held that manufacturer contract pharmacy policies *do not* constitute a violation of 340B. *See* HRSA ADR

Panel, *St. Croix Reg'l Med. Ctr.* Decision Summary (2025), https://tinyurl.com/3pvw43zd.

100. Against the backdrop of unfavorable federal outcomes, covered entities turned their sights to lobbying states to seek the very same benefits they are not owed under federal law. They seek to change the federal program by mandating that manufacturers take actions that even the federal agency tasked with 340B's administration and enforcement cannot require.

101. The repercussions of those efforts, if allowed to stand, will be intensified by the recently enacted Inflation Reduction Act ("IRA").[7] The IRA establishes the Medicare Drug Price Negotiation Program, under which HHS is to "negotiate" with manufacturers "maximum fair prices" for certain drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must provide access to selected drugs at the so-called maximum fair prices, except that they need not provide access to the maximum fair prices when such selected drugs are 340B-eligible and the 340B price is lower than the maximum fair price. *Id.* § 1320f-2(d). That is, manufacturers need not provide both the 340B price and "maximum fair price" on the same selected drug. *Id.* To avoid duplicate discounting, this scheme necessarily requires identifying when a

[7] Several of PhRMA's members have drugs that are subject to the IRA's Medicare Drug Price Negotiation Program, including Boehringer Ingelheim Pharmaceuticals, Bristol Myers Squibb Company, Astellas, Novo Nordisk, and Merck.

drug subject to the maximum fair price is dispensed as a 340B drug—further demonstrating the "interdependent nature" of Medicare and the 340B program. *Astra*, 563 U.S. at 120.

102. The Centers for Medicare and Medicaid Services ("CMS") has issued final IRA guidance for avoiding duplicate discounting under the Medicare Drug Price Negotiation Program. Under that guidance, a manufacturer bears the burden of determining and verifying whether a "claim for a selected drug is a 340B-eligible claim." CMS, Medicare Drug Pricing Negotiation Final Guidance ("Final Guidance") at 60, https://tinyurl.com/3sx8hmah; *see also* CMS, Medicare Drug Price Negotiation Program Draft Guidance ("Draft Guidance"), at 48 (A manufacturer must "indicate[] that the claim for [a] selected drug is a 340B-eligible claim and the 340B ceiling price is lower than the [maximum fair price] for the selected drug."), https://tinyurl.com/dapyyjyf. To facilitate the identification of 340B drugs, dispensing entities are encouraged to use claims codes indicating which drugs are dispensed under the 340B program, and to provide prescriber identification information to help manufacturers identify "whether a prescription was written by a prescriber with a high percentage of claims originating from a 340B covered entity." Draft Guidance at 41; Final Guidance at 45, 57. Commenters noted "that, under the nonduplication approach described by CMS in the draft guidance, [IRA] Manufacturers would likely mandate 340B claims data submission from covered

entities." Final Guidance at 57. "Many commenters strongly opposed CMS allowing for such mandates and stated that, at minimum, CMS should evaluate and regulate the data requirements imposed by [IRA] Manufacturers on covered entities." *Id.* In response to such comments, CMS stated it "will not prescribe a specific nonduplication approach that [IRA] Manufacturers must follow or impose parameters" on it, and noted in its justification that manufacturers bear the burden for ensuring nonduplication. *Id.* at 57-58; *id.* at 54 (stating CMS "will not assume responsibility for deduplicating discounts between the 340B ceiling price and the [maximum fair price]").

E. Hawai‘i Enacts H.B. 712 To Impose State-Law Conditions On 340B

1. H.B. 712's Passage And Requirements

103. On May 30, 2025, Hawai‘i enacted H.B. 712. It becomes effective on July 1, 2025. H.B. 712 Sec. 3.

104. H.B. 712 is targeted at and has the purpose and effect of regulating a federal program. Indeed, H.B. 712 is clear that its regulatory object is the federal 340B program and without that federal program, H.B. 712 would have no independent effect. *See* H.B. 712 Sec. 2, § 1 ("340B drug" means a "drug that is purchased by a 340B covered entity through the federal 340B drug pricing program authorized by title 42 United States Code section 256b and is dispensed by a

pharmacy"); *see also id.* Sec. 1 (noting that the purpose of the law is "to preserve the integrity of the 340B drug pricing program").

105. H.B. 712's prohibition is explicitly directed at manufacturers. It instructs that "[n]o manufacturer, or any agent or affiliate of a manufacturer, shall deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or shipping or delivery of a 340B drug to, a pharmacy that is under contract with a 340B covered entity and is authorized under the contract to receive and dispense 340B drugs on behalf of the 340B covered entity unless the receipt is prohibited by the United States Department of Health and Human Services." *Id.* Sec. 2, § 2(a).

106. H.B. 712 also provides that its restrictions do not "deny, restrict, or prohibit a manufacturer from requiring a 340B covered entity to provide claims data for the manufacturer's 340B drugs dispensed through a contract pharmacy arrangement" *but only where* "the claims data is necessary to investigate potential diversion, duplicate discounts, or whether a transaction is eligible for a rebate under applicable arrangements between a drug manufacturer and a third-party payor" and is limited to claims submitted "no more than three years prior to the date of the request." *Id.* Sec. 2, § 2(b).

2. Enforcement

107. H.B. 712 does not acknowledge the limitations on enforcement power that Congress deemed necessary to maintain the 340B program's delicate balance.

108. Instead, H.B. 712 empowers 340B covered entities and the Hawai‘i Attorney General to bring a civil suit to enforce the law. *Id.* Sec. 2, §§ 3-4. Put differently, H.B. 712 allows private entities to circumvent the ADR system established by Congress as 340B's sole enforcement mechanism, in direct contravention of *Astra*. *See* 563 U.S. at 118 ("The absence of a private right to enforce the statutory ceiling price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing.").

109. For a suit brought by a 340B covered entity, the civil remedies include injunctive relief and, if the 340B entity is successful, reimbursement for attorney's fees and costs. H.B. 712 Sec. 2, § 3.

110. For a suit brough by the Hawai‘i Attorney General, the civil remedies include a fine of up to $2,500 for each violation, with "[e]ach day that a violation" occurs counting as a "separate violation," along with disgorgement and "any other equitable relief that [the court] considers appropriate." *Id.* Sec. 2, §4(b)-(c).

111. These procedures and remedies extend far beyond the procedures and remedies the federal government may pursue under 340B. *See, e.g.*, 42 U.S.C. § 256b(d). This includes H.B. 712's requirement that "[e]ach day that a violation occurs" counts as a "separate violation." *Compare* H.B. 712 Sec. 2, §4(b)-(c) *with* 42 C.F.R. § 10.11(a) (allowing a civil monetary penalty "not to exceed $5,000 for each instance of overcharging").

112. H.B. 712 expressly predicates its purported addition of a state law obligation on the existence of an underlying federal obligation. *E.g.*, H.B. 712 Sec. 2, § 1.

113. As a result, in any state enforcement proceeding, a state adjudicator will be required to answer multiple questions of federal law to determine if a manufacturer violated H.B. 712. These include, among other things, whether under *federal* law (1) a particular covered entity has permissibly contracted with a contract pharmacy under federal law and has the necessary "principal-agent" relationship required to even arguably comply with federal law, 42 U.S.C. § 256b(a)(5)(A)-(B); (2) the covered entity continues to "hold title" to the 340B-priced drugs throughout all relevant transactions (which does not occur under the prevailing product "replenishment model"); (3) all of the individuals receiving 340B-priced drugs meet the federal definition of a 340B patient; (4) the particular prescriptions at issue qualify for 340B prices; and (5) the 340B price reductions are duplicative of Medicaid rebates applicable to the same prescriptions, *id.*§ 256b(a)(5)(A). A state adjudicator will also be required to determine if a covered entity continues to qualify for participation in the federal program. For example, a covered entity that sells or transfers 340B-priced drugs to anyone other than its patients is no longer eligible to receive 340B-priced drugs. *Id.* § 256b(a)(5). Similarly, covered entities violating prohibitions on duplicate discounts are ineligible to receive any 340B-priced drugs.

Id. § 256b(a)(4)-(5). Under H.B. 712, a Hawai‘i state adjudicator court will be required to make these determinations to adjudicate any purported violation of H.B. 712.

CLAIM FOR RELIEF

CLAIM I
(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution and the Federal 340B Statute)

114. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

115. Federal law is "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

116. H.B. 712 is preempted under the Supremacy Clause because it intrudes upon the exclusive field created by 340B and, worse, does so in a way that directly conflicts with the federal statute's terms and in a manner that is likely to generate conflict between state and federal regulators.

117. Field preemption exists where (1) Congress's "framework of regulation [is] 'so pervasive'" that Congress has "left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v.*

United States, 567 U.S. 387 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

118. Field preemption is especially likely where a state law "'diminish[es] the [Federal Government]'s control over enforcement' and 'detract[s] from the integrated scheme of regulation' created by Congress." *Arizona*, 567 U.S. at 402 (quoting *Wisc. Dep't of Indus. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986)).

119. As the Supreme Court has recognized, Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck. *See Astra*, 563 U.S. at 120 (noting the "interdependent" nature of 340B with other federal programs). No room exists for state supplantation in this field. Congress created the exclusively federal field here through enactment of 340B. *See supra* ¶¶ 33-57, 98. Unlike some other federal healthcare programs, where Congress has assigned the states significant roles in administering those programs, it chose not to do so here. *See, e.g.*, 42 U.S.C. § 1396a (Medicaid statute providing for state plans); *id.* § 18031 (Affordable Care Act establishing states' ability to set up health benefit plan exchanges).

120. The system crafted by Congress did not impose open-ended obligations on manufacturers. Instead, Congress designed a pervasive and integrated scheme of regulation through creation of a closed and limited system. Congress carefully

defined those eligible to receive 340B drugs (enumerated covered entities), set the nature of the benefit (obligation to offer drugs), and imposed limitations on that benefit (to whom covered entities may furnish 340B-priced drugs). Congress spoke in exacting detail because maintaining a delicate balance in the 340B program, given its interconnection with other federal programs, is essential to ensure that the program achieves its purpose without becoming too onerous for manufacturers. Finally, Congress set out an exclusive federal enforcement scheme to maintain the federal programs as a harmonious whole. Each of these features reinforces that the 340B program is an area of dominant federal concern.

121. H.B. 712 nevertheless seeks to directly intrude on this carefully balanced federal program by expanding and materially altering the scope of manufacturers' obligations and rights, and by implementing a competing enforcement regime. That is far more than 340B requires, permits, or contemplates. *Sanofi*, 58 F.4th at 703; *see also id.* at 706 (Third Circuit enjoining the federal government from mandating what Hawai‘i is now attempting to do).

122. That intrusion into the field of the operation of 340B is made clear by H.B. 712's scope. Hawai‘i pharmacies can freely order any drug available to them at market pricing. H.B. 712 does not seek to expand access to drugs generally—it merely seeks to compel 340B pricing for drug orders. In so doing, Hawai‘i attempts to forcibly insert itself into an arena occupied exclusively by the federal government

(*i.e.*, 340B's reticulated scheme setting forth who can receive 340B-priced drugs). But the federal 340B scheme leaves no room for state supplementation. H.B. 712's imposition of additional obligations and a separate enforcement scheme is accordingly preempted as an impermissible intrusion into a federally dominated field.

123. H.B. 712 is also conflict preempted. Conflict preemption arises when "[state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), or "interferes with the methods by which the federal statute was designed to" achieve those purposes and objectives, *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (state law preempted because it would "upset[] the balance of public and private interests so carefully addressed by the [federal statute]"). A conflict exists between the 340B statute and federal PPAs, on the one hand, and H.B. 712, on the other, for several reasons.

124. H.B. 712 disregards and conflicts with careful limitations in the federal regime, designed to maintain the delicate balance struck by Congress. As to covered entities, Congress sharply limited what they could do with 340B-priced drugs, prohibiting covered entities from reselling or transferring them to anyone other than their own patients. 42 U.S.C. § 256b(a)(5)(B). As to manufacturers, 340B requires only that manufacturers "offer" 340B-priced drugs to covered entities (*i.e.*, that they

provide some meaningful path for covered entities to access these medications). *See id.* § 256b(a)(1); *Novartis*, 102 F.4th 460-64; *Sanofi*, 58 F.4th at 703. The offers can include reasonable conditions, including both one contract pharmacy restrictions and a requirement that claims data be provided. *Novartis*, 2021 WL 5161783, at *8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of 340B-priced drugs); *id.* ("For its part, [the plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B."); *Novartis*, 102 F.4th at 463-64 (affirming holding); *Sanofi*, 58 F.4th at 704. As those decisions make clear, other types of conditions would also be permissible so long as they do not render an offer non-bona fide. Finally, Congress provided for an exclusive enforcement regime, which includes (among other things), the right of manufacturers to audit a covered entity. 42 U.S.C. § 256b(a)(5)(C).

125. H.B. 712's rewriting of the federal program's terms conflicts with the 340B statute in multiple ways and so is preempted. To name just a few, non-exhaustive examples:

126. *First*, H.B. 712 reworks manufacturers' obligations and rights under the federal program. Hawai‘i is now seeking to impose as a matter of state law a bar on conditions for contract pharmacy use, a bar even the federal government has been

enjoined from levying. *Sanofi*, 58 F.4th at 706; *see also Novartis*, 102 F.4th at 463-64 (explaining these reasonable conditions can be included as part of a manufacturer's 340B offer). By rewriting the terms of the required federal offer and barring manufacturers from including these conditions, H.B. 712 dramatically expands manufacturers' obligations under a federal program. As courts have recognized, this expansion of obligations under a federal incentive program is preempted. *Forest Park II v. Hadley*, 336 F.3d 724, 732-33 (8th Cir. 2003) (holding states may not impose additional obligations on participants in incentive-based, federal programs, even where the federal statute does not explicitly bar such additional obligations). Hawai'i's efforts both conflict with the plain text of 340B's requirements and stand as an obstacle to the carefully circumscribed and federally managed closed system Congress created.

127. Nor can H.B. 712 be saved by recasting it as a distribution requirement. Hawai'i is attempting to regulate who can receive 340B-priced drugs, not drugs in general. No one suggests that manufacturers will not provide market-priced drugs to pharmacies. The aim instead is to force manufacturers to provide those same drugs to those same pharmacies at a lower price. *Morrisey*, 760 F. Supp. 3d at 455-56 (recognizing that similar state statute was actually about forcing manufacturers to provide 340B pricing, not about delivery). Indeed, absent the pricing requirement, Hawai'i's law would be meaningless. *See* H.B. 712 Sec. 2, § 1 ("340B drug" means

a "drug that is purchased by a 340B covered entity through the federal 340B drug pricing program authorized by title 42 United States Code section 256b and is dispensed by a pharmacy"); *see also id.* ("340B entity" means "an entity that participates in the federal 340B drug pricing program authorized by title 42 United States Code section 256b (section 340B of the Public Health Service Act)"). A report by Hawai'i's House Committee on Judiciary & Hawaiian Affairs confirms as much. Hawai'i Stand. Comm. Rep. No. 1072 (Feb. 28, 2025), https://tinyurl.com/yazxyau8. It explains that H.B. 712 "deters behavior by manufacturers from restricting or denying access for pharmacies contracted with 340B covered entities *to purchase 340B drugs at discounted prices* under the federal 340B Drug Discounting Program." *Id.* at 2 (emphasis added).

128. And the text of H.B. 712, as well as how 340B operates, makes clear that H.B. 712 does not simply enact a delivery requirement. It applies to "340B drugs," defined as drugs "purchased . . . through the federal 340B drug pricing program." H.B. 712 Sec. 2, § 1. But, unless a covered entity (or a contract pharmacy purporting to act on its behalf) accepts a manufacturer's reasonable conditions on its 340B offer, there is no 340B purchase. *See supra* ¶¶ 4, 11, 91. Specifically, to even order a drug at a 340B price, a covered entity must first agree to reasonable conditions that are part of a drug manufacturer's offer, including, for example one-contract-pharmacy and claims data conditions. *Novartis*, 102 F.4th at 460-64

(recognizing that such conditions are permissible under federal law). If the covered entity agrees, it may purchase the drug at the 340B price. If it does not, the 340B offer is rejected and a purchase at the 340B price cannot occur. *Id.* In other words, if the buyer does not accept those conditions when attempting to place a 340B order, *there is no order placed and no 340B purchase.* That makes clear that H.B. 712 does not simply attach a "delivery" obligation—under the federal statutory framework, there is nothing for that delivery obligation to attach to. H.B. 712 thus seeks to compel drug manufacturers to make *340B-priced sales* in situations and under circumstances that federal law does not require.

129. *Next,* H.B. 712's state-law enforcement provisions conflict with the carefully calibrated system created by Congress to ensure 340B compliance and raise the specter of inconsistent adjudications. *See Morrisey*, 760 F. Supp. 3d at 453-60 (holding similar state law was preempted because it conflicted with 340B's enforcement regime). H.B. 712 impermissibly attempts to permit private suits to enforce 340B, despite the Supreme Court's determination that Congress explicitly chose not to permit private rights of action. *See supra* ¶¶ 17, 108. As the Supreme Court made clear, Congress chose not to authorize private rights of action, which would "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 120. Instead of permitting "340B entities to launch lawsuits in district courts across the country,"

Congress chose to "create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits[.]" *Id.* at 121. Despite that, Hawai'i purports to allow private entities to bring their own suits, creating the same "risk of conflicting adjudications" that prompted the Supreme Court to hold that private actions were barred no matter if the claims were "dressed" in other "clothing." *Id.* at 113-14, 120.

130. H.B. 712 also conflicts with Congress's chosen scheme of exclusive federal oversight for 340B. *See Astra*, 563 U.S. at 113; *see also Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-50 (2001) (where agency had "a variety of enforcement options that allow it to make a measured response," greenlighting state-law tort claims would "inevitably conflict with the [agency's] responsibility to police fraud consistently with [its] judgment and objectives"); *Morrisey*, 760 F. Supp. 3d at 453-60 (holding similar state law was preempted because it conflicted with 340B's enforcement regime). In *Astra*, covered entities operated by Santa Clara County brought suit to enforce 340B pricing against drug manufacturers directly rather than bringing that issue to HRSA. *See* 563 U.S. at 116-17. Two things happened. First, in response to such disputes, Congress stepped in and amended the 340B statute to add detailed administrative enforcement mechanisms—all to be overseen by HRSA, subject to federal court review. 42 U.S.C. § 256b(d). Second, the Supreme Court ruled against Santa Clara County, explaining that the new federal

agency administrative enforcement mechanisms were the "proper remedy" for disputes about the operation of 340B. *Astra*, 563 U.S. at 119-22. The Court stressed repeatedly that it was essential 340B be administered "harmoniously and on a uniform, nationwide basis." *Id.* at 120.

131. H.B. 712 conflicts with that regime in multiple ways. Like the claims considered in *Astra*, H.B. 712 conflicts with the federal enforcement regime by usurping the federal agency's unitary enforcement authority. Federal ADR regulations issued in 2024 make clear HRSA's view that it has federal statutory authority to address the same issues as H.B. 712, including through ADR. *See* 89 Fed. Reg. at 28,649 (defining overcharge claim, to be brought via ADR, to encompass "a claim that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price or the manufacturer does not offer the 340B ceiling price"); *see also supra* ¶ 99 (discussing recent ADR decision addressing these very same issues and finding contract pharmacy policy does not violate 340B). In other words, the federal government believes it has authority to address the same issues that H.B. 712 purports to regulate—when and under what terms 340B-priced drugs must be provided. *Id.*; 42 U.S.C. § 256b(d)(1) (covering "overcharges and other violations of the discounted pricing requirements"). Yet Hawai'i seeks to address the very same dispute, contra to *Astra*. *Morrisey*, 760 F. Supp. 3d at 453-59.

132. A preview of potential state enforcement proceedings drives the impermissible conflict home. Hawai‘i has tied H.B. 712 to 340B. Accordingly, determining whether a manufacturer violated H.B. 712 requires determining if there was an underlying 340B obligation in the first place. To make the latter determination, a decisionmaker will need to answer several federal law questions, including: (1) whether the drugs are actually covered outpatient drugs under 340B; (2) whether they are eligible for 340B pricing; (3) whether the manufacturer provided the 340B price; (4) whether a covered entity is a 340B covered entity under federal law; and (5) whether there has been diversion or duplicate discounting (which includes determining whether a specific drug was distributed to a covered entity's "patient"). *Morrisey*, 760 F. Supp. 3d. at 458-59; *Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *2 (D.D.C. May 15, 2025) (noting requirements for an individual to qualify as a patient of a covered entity).

133. Hawai‘i's restriction on the collection of claims data, unless it "is necessary to investigate potential diversion, duplicate discounts, or whether a transaction is eligible for a rebate under applicable arrangements between a drug manufacturer and a third-party payor" further conflicts with the unitary federal enforcement regime. H.B. 712, Sec. 2, § 2(b). As other courts have recognized, claims data plays a vital role in maintaining program integrity and manufacturers need claims data to access the federal enforcement regime. *See Morrisey*, 760 F.

Supp. 3d at 450-53 (holding state law that barred collection of claims data was preempted because it conflicted with manufacturers' audit rights and restricted access to the federally administered ADR system); *Eli Lilly*, 2025 WL 1423630, at *2-4, *12-14 (affirming manufacturers' right to "impose data-reporting conditions on covered entities," explaining why claims data is important to maintaining program integrity, and requiring federal agency to take it into account when considering how manufacturers can structure their program participation).

134. Under the federal regime, manufacturers must first audit a covered entity before initiating ADR. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv). However, manufacturers are only permitted to conduct an audit where they "ha[ve] documentation which indicates there is reasonable cause." 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). "Reasonable cause" is defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibition on transfer or sale, or the prohibition on duplicate discounting. *Id.* Accordingly, to even access the audit process to engage in an ADR proceeding, manufacturers must be able to access information that will allow them to determine if reasonable cause exists to suspect a covered entity is violating 340B's provisions.

135. Notwithstanding that, H.B. 712 sets up state decisionmakers—rather than Congress or federal officials—as the arbiter of what claims data can be collected by manufacturers. It thus directly conflicts with Congress's intended unitary

administration and enforcement of 340B. And it directly injures manufacturers by requiring them to justify their claims data conditions not only to the sole administrator, superintended by federal courts, contemplated by Congress but also separate decisionmakers, in a potential multitude of private actions, that would each create the very "risk of conflicting adjudications" that the Supreme Court warned against in *Astra*, 563 U.S. at 120.

136. Hawai'i may contend that it carves out the collection of claims data for specific investigatory purposes and so the restriction is not preempted. Of course, because the prohibition invades the federal field of the operation of 340B, it remains subject to field preemption. *See supra* ¶¶ 117-22. But the exception for investigatory purposes also does not save the restriction from conflict preemption. H.B. 712 still distorts 340B's administration and enforcement scheme by allowing separate decisionmakers to adjudicate whether manufacturers' collection of claims data is proper under the federal program and imposes time restrictions on when claims data may be collected. Indeed, the *Morrisey* court addressed whether a state could save its claims data prohibition from conflict preemption by including a so-called savings clause[], which provided that the collection of claims data was not prohibited if it was "required by the United States Department of Health and Human Services." 760 F. Supp. 3d at 459 n.7 (quoting W. Va. Code § 60A-8-6a(b)(2)). As the court held, even with that "savings clause," the state law still "upset[] the

carefully crafted regulatory scheme of Congress." *Id.* The same is true here. Given that the federal enforcement regime is overseen by HHS and it is that agency, within Congressional limits and overseen by federal courts, that determines whether there is "reasonable cause" to initiate an audit, allowing state decisionmakers to determine what claims data a manufacturer may collect presents a direct conflict with 340B's unitary enforcement regime.

137. H.B. 712 also skews the carefully balanced enforcement scheme enacted by Congress. Congress specified certain limited civil penalties that could be levied in limited circumstances. 42 U.S.C. § 256b(d)(1)(B)(vi)(II) (setting a maximum of $5,000 per violation). Yet, H.B. 712 allows for a penalty of up to $2,500 for each violation, with "[e]ach day that a violation" occurs constituting a "separate violation" as well as "disgorgement." H.B. 712, Sec. 2, § 4(b), (c). The layering on of additional adjudicators and penalties wildly unbalances Congress's system, and threatens the same inconsistent adjudications identified in *Astra* because Hawai‘i cannot enforce H.B. 712 without adjudicating multiple questions of federal law.

138. *Finally*, H.B. 712 frustrates the "accomplishment and execution of the full purposes and objectives of Congress," *Hines*, 312 U.S. at 67, in various ways in addition to those described above. For example, by purporting to impose additional, onerous terms and limitations on 340B (which the Third Circuit has held not even

the federal government can impose), H.B. 712 increases the cost of manufacturer participation in the federal Medicare Part B and Medicaid programs. And H.B. 712's mandate will contribute to duplicate discounts and diversion of 340B drugs to ineligible recipients, both of which the federal scheme forbids.

139. For all of these reasons and more, H.B. 712 is preempted, and its enforcement should be enjoined.

PRAYER FOR RELIEF

PhRMA respectfully prays that this Court:

a. issue an order and judgment declaring that H.B. 712 is unconstitutional and violates federal law;

b. issue an order and judgment declaring that H.B. 712's provisions are unlawful as to PhRMA's members covered outpatient drugs sold through the 340B Drug Pricing program;

c. enjoin, preliminarily and permanently, the implementation and enforcement of H.B. 712 against PhRMA's members and members' affiliates, officers, agents, representatives or contractors;

d. enjoin, preliminarily and permanently, the implementation and enforcement of H.B. 712 as to the sale of PhRMA's members' drugs under 340B;

e. award PhRMA costs and reasonable attorneys' fees, as appropriate; and

f. grant any other relief the Court finds just and appropriate.

DATED: Honolulu, Hawaii, July 11, 2025.

/s/ *Matthew D. Ezer*

EDMUND K. SAFFERY
WAYNE R. WAGNER
MATTHEW D. EZER

PHILLIP J. PERRY (*phv* forthcoming)
ANDREW D. PRINS (*phv* forthcoming)
ABID R. QURESHI (*phv* forthcoming)

Attorneys for Plaintiff
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA